EXHIBIT C

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EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Bern Ripka Law Firm to give medical opinions related to Melissa Ridgely. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

As stated above, I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the autologous fascial-based pubovaginal sling. I have attending training provided by Ethicon, Inc. regarding the TVT device. In addition, I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the

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patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and a deposition with accompanying exhibits pertaining to Melissa Ridgley:

- Lafayette Home/Saint Elizabeth's Hospital, Imaging Records, 7/23/2002-3/29/2012
- FDA Maude Adverse Event Report, 4/26/2010
- Family Practice Center, Annual H and P, 5/26/2004
- Lafayette Ob/Gyn Medical Records, 1/20/2006
- Saint Vincent Gyn-Onc Medical Records, 2/13/2006-3/6/2006
- Woman's Clinic Medical Records, 1/11/2007-2/28/2013
- Arnett Surgery Center Operative Report, 2/28/2007
- Urology of Indiana Medical Records, 2/2/2010
- Lafayette Clinic of Urology Medical Records, 7/8/2011
- Unity Radiology Medical Records, 3/20, 2013

In addition I have reviewed the following medical literature and other TVM related documents and have relied, in part, on the documents below in addition to my medical and clinical experience in forming my opinions:

- AMA 8.08
- TVT Instructions for Use, 2009
- C.G. Nilsson et al "Seventeen years' follow-up of the tension free vaginal tape procedure for female stress urinary incontinence." Int. Urogynecol. J. (2013) 24:1265-69
- P. Hilton "A clinical and urodynamic study comparing the Stamey bladder neck suspension and suburethral sling procedures in treatment of genuine stress incontinence" British Journal of Obst. & Gynecol (February 1989, Vol 96, pp. 213-220
- H. Enzelsberger et. al "Comparison of Burch and Lyodura Sling Procedures for Repair of Unsucessful Incontinence Surgery" Obstet & Gynecol, Vol 88, No. 2, August 1996
- A.S. Arunkalaivanan et al "Randomized trial of porcine dermal sling (Pelvicol implant) vs. Tension-free Vaginal Tape (TVT) in the Surgical treatment of stress incontinence: a questionnaire based study" Int. Urogynecol J (2003), 14: 17-23

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Matthew Whang, MD
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- K. Guerrero et al "A randomized controlled trial comparing two autologous fascial sling techniques for the treatment of stress urinary incontinence in women: short, medium and long-term follow-up" Int. Urogynecol J (2007) 18:1263-1270
- B. Welk et al, "Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence" JAMA Surgery, Published Online September 9, 2015.
- E. Petri et al., "Complications of synthetic slings used in female stress urinary incontinence and applicability of the new IUGA-ICS classification" Eur. J. of Obstet. & Gynecol. and Reprod. Bio. 165 (2010) 347-351
- B. Klosterhalfen et al., "Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair" Biomaterials (1998) 2235-46
- J. Anger et al., "Complications of Sling Surgery Among Female Medical Beneficiaries" Obstet. & Gynecol. Vol. 109, No. 3 (March 2007)
- P. Moalli et al, "Tensile Properties of five commonly used mid-urethral sling relative to the TVT" Int. Urogynecol J (2008) 19:655-663
- A. Clave et al, "Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants" Int. Urogynecol J (2010) 21:261-270
- O. Chinthakanan et al., "Mesh Removal Following Sling/Mesh Placement: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-139-40
- O. Chinthakanan et al, "Indication and Surgical Treatment of MidUrethral Sling Complications: A Multicenter Study" Int. Urogynecol. J (2014) 25 (Suppl 1) S-142-43
- E. Petri et al., "Comparison of late complications in retropubic and transobturator slings in stress urinary incontinence" Int. Urogynecol. J. (2012) 23:321-325
- S. Abbott et al., "Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: a multicenter study" American J. of Obset. & Gynecol (February 2014) 163.e1-8.
- G. Agnew et al, "Functional outcomes following surgical management of pain, exposure or extrusion following a suburethral

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tape insertion for urinary stress incontinence" Int. Urogynecol J. (2014) 25:235-239

- J. Duckett et al, "Pain after suburethral sling insertion for urinary stress incontinence" Int. Urogynecol J. (2013) 24:195-201
- C. Skala et al., "The IUGA/ICS classification of complications of prosthesis and graft insertion" Int. Urogynecol J (2011) 22:1429-1435
- K. Svabik et al., "Ultrasound appearances after mesh implantation – evidence of mesh contraction or folding?" Int. Urogynecol J. (2011) 22:529-533
- A. Rogowski et al., "Mesh retraction correlates with vaginal pain and overatice bladder symptoms after anterior vaginal mesh repair" Int. Urogynecol. J. (2013) 24:2087-2092
- F. Daneshgari et al., "Surgery for Urinary Incontinence in Women", 3rd International Consultation on Incontinence, 2005, chapter 20

In addition, I have reviewed the deposition of Dr. Martina Mutone.

Clinical History

- On May 26th, 2004 Mrs. Ridgley had complaints of dyspareunia and vaginal bleeding after intercourse

- On January 20th, 2006, Mrs. Ridgley visited Dr. Watson with complaints of stress urinary incontinence, vaginal bleeding, and irregular periods.

- On March 6th, 2006, Mrs. Ridgley underwent a radical trachelectomy with lysis of adhesions, cervical cerclage, suprapubic tube placement, and pelvic lymph node dissection revealing stage T1B1 cervical adenocarcinoma. This surgery was performed by Dr. Gregory Sutton.

- On February 28th, 2007, Mrs. Ridgley underwent operative laparoscopy with lysis of adhesions, performed by Dr. Michael Henry.

- On January 30th, 2008, Mrs. Ridgley underwent a right salpingo-oophorectomy, lysis of adhesions, and appendectomy, performed by Drs. Daniel Sunkel and Jerry Jefson.

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- On August 11th, 2009, Mrs. Ridgley underwent a vaginal biopsy, revealing endometriosis.

- On February 2nd, 2010, Mrs. Ridgley presented to the Urology of Indiana practice with complaints of voiding dysfunction and urinary incontinence. She was examined by Dr. Martina Mutone who performed a standing stress test documenting leakage with cough and weak pelvic muscles. She had apost-void residual of 10 milliliters. There were no pelvic masses, no pelvic pain was documented during exam, nor were there findings of atrophic vaginitis and the patient had a normal rectal exam. In addition, she was found to have hematuria.

- On April 26th, 2010, Dr. Sutton performed an abdominal hysterectomy, left salpingo-oophorectomy and repair of incidental cystotomy. Dr. Martina Mutone performed a TVT-sling procedure and cystoscopy given clinical findings consistent with stress urinary incontinence. Dr. Mutone memorialized a thorough informed consent including discussions regarding mesh-related complications as discussed in her deposition. During the procedure, Dr. Mutone also memorialized that the patient's vaginal epithelium was very thin and tore easily, especially on the left side. After the sling was set in a tension free fashion, the vaginal epithelium was trimmed and repaired using absorbable suture material.

- On December 13th, 2010, Dr. Mutone performed a revision of Mrs. Ridgley's sling, removing a 1.5 cm piece of mesh that had eroded in the area of the mid-urethra on the left side of the vagina.

- On March 25th, 2011, Mrs. Ridgley saw Dr. Mutone with complaints of SUI, incomplete bladder emptying, urinary frequency, and difficulty urinating. Physical exam documented no mesh erosion and a post-void residual of 60 milliliters. She was offered alternative treatment options for her SUI including periurethral bulking.

Methodology

My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

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My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause.

General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2010 was not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Transitory local irritation at the wound site may occur.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection.
- Over correction, i.e., too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which in some patients may not resolve.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.

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- Recurrence of incontinence
- Bleeding including hemorrhage, or hematoma.
- One or more revision surgeries may be necessary to treat these adverse reactions.
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required.
- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse.
- Death

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The TVT IFU does not mention: mesh contraction; the severity of mesh-related dyspareunia; mesh shrinkage. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events or the particular role mesh plays in mediating these adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2010 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy. Although Dr. Mutone testified in her deposition that she found the TVT sling to be safer in her hands, she was not clinically engaged in the performance of native tissue repairs such as the autologous fascial slings (last performed 4 years ago) or the Burch procedure (performed 6-7 years ago). In fact, she never performed a Marshall-Marchetti-Krantz procedure, another non-mesh based repair for SUI. Simply because

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the TVT procedure could be performed on an outpatient basis, present lower risks of urinary retention (which this patient had), and be performed more quickly does not preclude the patient the right to explore other surgical options that would offer a different adverse event profile.

Contrary to Dr. Mutone's opinion that autologous slings are less effective than mesh slings, there is ample data to support that autologous fascial slings can provide effective long term cure of SUI, as put forth by Daneshgari and colleagues on behalf of the International Continence Society.

Case Specific Opinion No. 1

Mrs. Ridgley suffered vaginal sling erosion, contraction, and failure of the TVT to incorporate, as a result of the physical properties of the TVT device. These conditions are documented in the medical records.

A. Erosion.

Dr. Mutone's operative note clearly documents an area of eroded mesh that she removed and submitted to pathology.

I have observed erosions caused by midurethral slings including the TVT sling, and other forms of transvaginal mesh, in my clinical practice.

B. Contraction/Shrinkage

Mrs. Ridgley's sling showed evidence of contraction or shrinkage. Urinary retention can develop in patients as a result of mesh contraction and/or scar plate formation. Although the presence of scar plate formation is not present in the reviewed medical records, Dr. Mutone's operative note memorializes that the ends of the mesh remaining retracted up behind the pubic bones, consistent with mesh contraction.

I have observed mesh contraction and shrinkage in my clinical practice.

C. Failure to Incorporate

Portions of the TVT device failed to incorporate into Mrs. Ridgley's surrounding tissues. As evidenced by her clinical course, Mrs. Ridgley suffered an erosion event less than 6 months post-implantation. Of interest, there was no foreign body response or inflammatory tissue around the area of mesh removed by Dr. Mutone. This is reflected in the pathology report which describes a 1.5 by 0.5 by 0.2 cm piece of mesh with adherent red-brown blood but no tissue present.

I have observed failure of mesh to incorporate in my clinical practice.

Case Specific Opinion No. 2

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Mrs. Ridgley's erosion in 2010 was caused by the physical properties of the TVT. Recognized causes of sling exposure include: (1) a surgical error in implantation technique; (2) atrophy of the vaginal tissue surrounding the device; and (3) the physical properties of the device post-implantation including, but not limited to, retraction, shrinkage, contraction, fraying, roping and curling.[1]

I am able to rule in the physical properties of the TVT, including the contraction of the TVT mesh, based on the discussion set forth in Case Specific Opinion No. 1.

I am able to rule out vaginal atrophy as a cause of Mrs. Ridgley's extrusion in 2010. Mrs. Ridgley's annual exams from 2004-2010 do not mention atrophic changes to Mrs. Ridgley's vaginal tissues. In addition, during her revision surgery, there were no findings of atrophic vaginitis.

I am able to rule out surgical error as a cause of Mrs. Ridgley's extrusion in 2010. Mrs. Ridgley was implanted with the TVT device on April 26th, 2010. Dr. Mutone documented that the vaginal epithelium was very thin and tore easily especially on the left side. Ultimately this was repaired without complication. She placed the sling in a tension-free fashion, as evidenced by the use of a number 7 Hegar dilator used as spacer when the sling was placed. This is a tensioning technique described in the TVT IFU.

During the procedure, the plastic sheath surrounding the mesh shredded during removal, making the removal of the sheath difficult. This resulted in a MAUDE adverse event report which was submitted to the FDA. No adverse patient consequences were reported. Taking the above findings into account, I am able to exclude surgeon error in 2010 as playing a causal role in the development of an erosion later that year.

Case Specific Opinion No. 3

Mrs. Ridgley's future prognosis as it relates to her SUI and voiding dysfunction is guarded. Because her post-void residuals are modestly elevated (at her last appointment with Dr. Mutone in April of 2011- 60 milliliters, increased from 10 cc prior to her sling surgery), care must be taken when considering an autologous fascial sling or other procedures (not involving synthetic mesh) for incontinence. Autologous fascial slings are contraindicated in patients with elevated post-void residuals because they are likely to worsen this condition or even create urinary

[1] *See* (Ashok, 2012)

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retention which she already suffered from post-mesh sling. For this reason, Mrs. Ridgley is not an ideal candidate for this type of surgery and may be best treated with medical therapy in combination with lifestyle modifications and pelvic floor physiotherapy. Although these interventions should be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from. In summary, within a reasonable degree of medical certainty, the voiding dysfunction and SUI will be a lifelong condition for this patient.

Sincerely,

Konstantin Walmsley, M.D.
February 29, 2016